

Message Text

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ACTION EB-07

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FM AMEMBASSY TOKYO

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FROM BLOOM AND THOMASSON

DEPT AGRICULTURE FOR HUME AND FITZSIMMONDS

E.O. 11652: N/A

TAGS: ETRD EAGR JA

SUBJ: CITRUS/FUNGICIDES

REF: (A) TOKYO 16845 (B) TOFAS 773

SUMMARY: EMBOFF IMPRESSIONS AFTER MTG MHW ARE (A) MHW NOT USING MUTAGENCY AS NTB AND (B) U.S. SHOULD SEND SCIENTIFIC TEAM FOR FURTHER DISCUSSIONS.

1. EMBASSY APPROACHED MHW OFFICIALS AT TECHNICAL LEVEL TO DISCUSS IMPLICATIONS AND WORDING OF PROVISIONAL STANDARDS ON MUTAGENCY (SEE REF B) AS APPLIED TO TBZ AND OPP. ON 11/21, SCICOUNS (J. BLOOM) AND AGATTS PAID CALL ON DR T. MATSUURA, DIR-GENERAL AND DR K. MIYAZAWA. JOINTED LATER BY DR H. KURATA, CHIEF, DEPT OF MICROBIOLOGY, NATIONAL INSTITUTE OF HYGIENIC SCIENCES. DURING MTG LASTING MORE THAN 2 HRS, SCICOUNS RAISED QUESTIONS RE LANGUAGE OF STANDARDS, POINTING OUT THEY ARE INSUFFICIENTLY CLEAR TO PERMIT TESTING LABORATORIES TO PREPARE EXPERIMENTAL DESIGN AND PROCEDURES WHICH COULD BE PRESUMED TO BE ACCEPTABLE TO GOJ AUTHORITIES.

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2. RESPONSES TO QUESTIONS RAISED CONVINCED EMBOFFS THAT

ALTHOUGH LANGUAGE OF STANDARDS IS QUITE OBSCURE, MHW IS SERIOUS ABOUT APPLYING THEM TO USE OF AGRICULTURAL CHEMICALS IN BOTH PRE-AND POST-HARVEST TREATMENT OF DOMESTIC AND IMPORTED FOODS AND IS NOT AT PRESENT USING THEM AS NOT. FOLLOWING INFO WAS OBTAINED:

3. THE NEW STANDARDS FOR TESTING OF MUTAGENICITY OF FOOD ADDITIVES WERE ADOPTED PROVISIONALLY LAST FALL (1974) BY FOOD SANITATION INVESTIGATION COUNCIL AND ARE NOW OFFICIAL. SO FAR, STANDARDS HAVE NOT BEEN APPLIED TO FOOD ADDITIVES PER SE (I.E., CHEMICALS USED IN POST-HARVEST TREATMENT OF AGRICULTURAL PRODUCTS), BUT 10 AGRICULTURAL CHEMICALS (I.E., FOR PRE-HARVEST TREATMENT) NOW IN COMMERCIAL USE ARE UNDER TEST BY MANUFACTURERS AT REQUEST OF MHW. ONE CHEMICAL BEING TESTED IS DIPHENYL. PROCEDURE USED IN THESE CASES INVOLVES FIRST AND SECOND SCREENING TESTS (CULTURING OF MUTAGEN-SENSITIVE BACTERIA, STUDIES OF CHROMOSOME ABERRATION IN MAMMALIAN CULTURED CELLS, TESTING OF SEX-LINKED RECESSIVE LETHAL MUTATION IN DROSOPHILA, AND TESTING OF RECESSIVE VISIBLE MUTATION IN SILKWORMS), FOLLOWED BY HOST-MEDIATED TEST OF CHEMICALS IN MAMMALS AND IN-VIVO CHROMOSOME ABERRATION TESTS IN MAMMALS. IF MAMMALIAN TESTS GIVE POSITIVE RESULTS, THEN DOMINANT LETHAL TESTS IN MICE AND RATS MUST BE CARRIED OUT.

4. ALTHOUGH FOOD ADDITIVES HAVE NOT BEEN SUBJECTED TO COMPLETE STANDARD, COUNCIL HAD REQUESTED DATA ON MUTAGENICITY TESTING OF SACCHARINE CARRIED OUT IN OTHER COUNTRIES AND HAD DIRECTED MHW SCIENTISTS TO CONDUCT FIRST AND SECOND SCREENING TESTS. PARTICULAR ATTENTION WAS PAID TO WORK OF SHUBIK (PHENETIC) IN U.S., WHO REPORTED FAVORABLY ON SACCHARINE AT WHO MEETING IN 1974. SHUBIK PAPER WAS DISCUSSED AT JULY 1975 MEETING OF COUNCIL.

5. MHW OFFICIALS RECOGNIZED THAT INTERNATIONAL REQUIREMENT FOR MUTAGENICITY TESTING OF CHEMICALS NOT YET ESTABLISHED, BUT TREND WAS IN THIS DIRECTION AS EVIDENCED BY ATTENTION BEING PAID BY WHO TO THIS SUBJECT.

6. WHEN SCICONS QUESTIONED MEANING OF TERM QUOTE CRITICAL IMPORTANCE UNQUOTE USED IN STANDARDS IN DETERMINING WHICH OF LIMITED OFFICIAL USE

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THE SEVERAL TESTS DESCRIBED ARE ACTUALLY REQUIRED, MHW SAID THAT THEY BELIEVED THAT AS MINIMUM THE FIRST AND SECOND SCREENING TESTS PLUS THE MAMMALIAN TESTS THROUGH THE DOMINANT LETHAL TEST ARE NEEDED, EXCEPT THAT DROSOPHILA TEST NOT NEEDED FOR AGRICULTURAL CHEMICALS. ALL CHEMICALS PREVIOUSLY APPROVED BY MHW WILL BE SUBJECTED TO THESE TESTS. IN CASE OF FOOD ADDITIVES, ALL TESTS THROUGH DOMINANT LETHAL REQUIRED, EXCEPT FOR SILKWORM TEST IF TESTING IS DONE IN U.S. LABORATORIES.

MHW BELIEVES THAT MICROORGANISM AND CELL CULTURES ARE NEEDED, SINCE IF THEY GIVE POSITIVE RESULTS THEY MAY BE INDICATIVE OF CARCINOGENICITY OR TERATOGENICITY, EVEN IF NOT OF MUTAGENICITY, AND COUNCIL WILL THEREFORE BE HESITANT TO APPROVE CHEMICALS WITHOUT SUCH TESTS.

7. SCICOUNS POINTED OUT THAT STANDARDS ARE VAGUE AS TO ACCEPTABLE EXPERIMENTAL PROTOCOLS FOR CONDUCT OF TESTS. NO LITERATURE REFERENCES ARE CITED, FOR EXAMPLE. MHW SCIENTISTS AGREED, AFTER CONSIDERABLE DISCUSSION THAT U.S. COMPANIES WISHING TO OBTAIN APPROVAL FOR USE OF CHEMICALS COULD PREPARE PROTOCOLS AND SUBMIT THEM TO MHW FOR REVIEW. WHEN THIS PROCEDURE WAS QUESTIONED AS BEING TIME-CONSUMING AND SUBJECT TO BACK-AND-FORTH DEBATE, MHW OFFICIALS SAID THAT ANY PROTOCOLS SUBMITTED WOULD BE REVIEWED BY COUNCIL WITHIN SEVEN DAYS AFTER RECEIPT. THEY FURTHER AGREED THAT GOJ SCIENTISTS WOULD BE WILLING TO MEET WITH US SCIENTISTS TO DEVELOP PROTOCOLS ON MUTUALLY SATISFACTORY BASIS, TO REDUCE CHANCE OF REJECTION BY COUNCIL. KURATA SAID THAT HE AND OTHER JAPANESE MICROBIOLOGISTS ARE PARTICULARLY IMPRESSED BY PAPER GIVEN IN CZECHOSLOVAKIA BY DR V. RAY, PFIZER COMPANY MEDICAL RESEARCH LAB, EASTERN POINT ROAD, GROTON, CONN., ON MUTAGENICITY TESTING. KURATA HAS REQUESTED REPRINT WHICH HAS NOT BEEN RECEIVED YET.

8. MIYAZAWA AND KURATA WERE ALSO QUESTIONED ABOUT DATA WHICH COULD BE EMPLOYED TO DETERMINE POPULATION DOSE OF CHEMICALS USED IN TREATMENT OF CITRUS FRUITS. THEY USE FIGURE BASED ON 1973 STATISTICS OF 90 GRAMS PER PERSON PER DAY OF CITRUS FRUIT COMSUMPTION, INDEPENDENT OF TYPE OF FRUIT, SEX OR AGE

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OF CONSUMER, OR COUNTRY OF ORIGIN OF FRUIT. AVERAGE WEIGHT OF JAPANESE IS TAKEN TO BE 50 KILOGRAMS. IF TBZ AND/OR OPP ARE TO BE APPROVED FOR USE ON IMPORTED FRUITS, IT IS TO BE ASSUMED THAT TREATMENT WILL BE APPROVED FOR DOMESTICALLY RAISED CITRUS FRUITS AS WELL, SO TOTAL CONSUMPTION MUST BE USED IN CALCULATIONS. TBZ IS ALREADY APPROVED FOR USE IN PRE-HARVEST TREATMENT OF SUGAR BEETS, CITRUS FRUITS (MIKAN ORANGES), AND PEARS IN JAPAN. WHEN MENTION WAS MADE BY EMBOFFS THAT TBZ IS USED FOR PRE-AND POST-HARVEST TREATMENT OF BANANAS, MHW OFFICIALS SAID THAT IT HAD NOT BEEN QTE FOUND UNQTE IN IMPORTED BANANAS, AND U.S. COMPANIES COULD ASSUME THAT CITRUS FRUITS AS A CLASS WOULD BE ONLY SOURCE OF TBZ CONTAMINATION.

9. EMBASSY COMMENT: MHW OFFICIALS CONTACTED ARE SCIENTISTS AND NOT PRIMARILY POLITICIANS. THEY SEEM DEDICATED TO PROPOSITION THAT AGRICULTURAL CHEMICALS AND FOOD ADDITIVES MUST BE TESTED FOR MUTAGENICITY AS CONSISTENT WITH WORLD-WIDE TREND. (IN THIS RESPECT, EMBOFF HAS BEEN TOLD BY PROMINENT US GENETICIST CURRENTLY IN JAPAN THAT USFDA IS CURRENTLY REVIEWING GRAS LIST TO DETERMINE WHICH ADDITIVES SHOULD BE SUBJECTED TO MUTAGENICITY TESTING. IF THIS IS TRUE, WE ARE HARDLY IN GOOD POSITION TO OBJECT STRENUOUSLY TO GOJ FOLLOWING SAME PRACTICE). PENDING OBTAINING EVIDENCE NOT NOW AVAILABLE THAT GOJ IS APPLYING NEW STANDARDS ON SELECTIVE BASIS AS NTB, EMBASSY BELIEVES THAT DEPT OF AGRICULTURE, INVOLVED US CHEMICAL LIMITED OFFICIAL USE

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MANUFACTURES, AND CITRUS FRUIT PRODUCERS SHOULD ASSEMBLE REPRESENTATIVE TEAM OF SCIENTISTS TO WORK OUT MUTUALLY ACCEPTABLE TEST PROTOCOLS WITH JAPANESE SCIENTISTS. KURATA STATES THAT MINIMUM OF FOUR JAPANESE SCIENTISTS REQUIRED: MICROBIOLOGISTS, CYTOGENETICIST, MAMMALIAN GENETICISTS, AND GOJ/MHW SUPERVISORY SCIENTIST. IT HAS NO PROBLEM WITH US USING MIXTURE OF GOVERNMENT AND INDUSTRY SCIENTISTS IN COUNTERPART GROUP. VISIT TO JAPAN BY US SCIENTISTS WOULD BE WELCOMED BY MHW. OBVIOUSLY, IF SUCH A WORKING MEETING IS HELD, IT IMPLIES THAT US IS NOW RESIGNED TO ACCEPTING GOJ REQUIREMENT FOR MUTAGENICITY TESTING AND THE DELAY REQUIRED TO CONDUCT TESTS. EQUALLY OBVIOUS IS SURMISE THAT IF MUTAGENICITY TESTING GIVES POSITIVE RESULTS, CITRUS PRODUCERS MAY EXPECT THAT CONTROLS WILL BE PLACED ON USE OF TBZ AND/OR OPP BY USG AND OTHER COUNTRIES.

10. ACTION SUGGESTED: SEND REPRESENTATIVE TEAM OF SCIENTISTS ASAP. IF POSSIBLE, TEAM SHOULD PREPARE TEST PROTOCOLS TO HAVE

READY FOR MHW REVIEW UPON THEIR ARRIVAL. TEAM SHOULD ARRIVE
HERE IF POSSIBLE BEFORE DEC. 10 IN ORDER TO ALLOW SUFFICIENT TIME FOR
DESCUSSIONS BEFORE JAPANESE NEW YEARS HOLIDAYS. OTHERWISE
TRIP SHOULD BE SCHEDULED FOR MID JAN 76.
HODGSON

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